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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,526	01/23/2007	Judith Boston	9618a	6984

20995 7590 10/05/2009  
KNOBBE MARTENS OLSON & BEAR LLP  
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EXAMINER
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CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

NOTIFICATION DATE	DELIVERY MODE
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10/05/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/574,526	<b>Applicant(s)</b> BOSTON, JUDITH	
	<b>Examiner</b> FRANK I. CHOI	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 89-149 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 89-149 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/10/2009 has been entered.

#### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) needs to be filed which in addition to identifying this application by application number and filing date also includes the date the preliminary amendment was filed, i.e. 3/31/2006. See MPEP §§ 602.01 and 602.02.

The Applicant filed a preliminary amendment on 3/31/2006 in which the PCT/US2004/032375 application was incorporated by reference and all other references cited in the application were incorporated by reference. The Specification and drawings do not contain said incorporation by reference statements. Since the Application was filed after 9/21/2004, the preliminary amendment is part of the disclosure as it was present at the time the application was filed. However, where a preliminary amendment contains subject matter not otherwise included in the specification and drawings of the application, the applicant must provide a supplemental oath or declaration under 37 CFR 1.67 referring to such preliminary amendment. See MPEP Section 608.04(b) [R-3]. The Application contains additional subject matter because mere citation to an application or other reference does not serve to incorporate the subject matter of said reference. Since the application and other references are now incorporated by reference, the

preliminary amendment added subject matter that was not otherwise included in the Specification and drawings.

***Claim Objections***

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Claims 89-132 were previously submitted by amendment on 3/31/2008.

Misnumbered claims 89-105 have been renumbered as claims 133-149. As such, the claims pending in this application are claims 89-149.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 89-149 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Specification does not enable methods of medical treatment and compositions for medical treatment containing tetrameric oxygen (O<sub>4</sub>). New Claims 133-149 do not explicitly state that the oxygen is tetrameric oxygen. However, since the Specification and claims as originally filed indicated that

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the oxygen was tetrameric oxygen, the enablement rejection applies to the extent the scope of new claims 133-149 include tetrameric oxygen.

*The nature of the invention:*

The invention is directed to method of using as a medical treatment and compositions for use in medical treatment containing tetrameric oxygen (O<sub>4</sub>).

*The state of the prior art and the predictability or lack thereof in the art:*

There does not appear to be any prior art directed to the use of tetrameric oxygen (O<sub>4</sub>) as claimed. Further, there is insufficient evidence to establish that O<sub>4</sub> exists, much less be prepared and/or isolated. At most, the existence of O<sub>4</sub> has been theorized, however, the disclosed stability is in the realm microseconds. As such, even if O<sub>4</sub> does exist, because the molecule would only exist for microseconds, there does not appear to be any practical method of preparing a composition which can be used to treat a given condition. See Schroder, pp. 573-574.

*The amount of direction or guidance present and the presence or absence of working examples:*

The Specification alleges that there is a product containing O<sub>4</sub> in an aqueous solution, however, said assertion is suspect in view of the above.

*The breadth of the claims and the quantity of experimentation needed:*

The claims are broad in that they claim the use of tetrameric oxygen. As such, in light of the above, one of ordinary skill in the art would be required to do undue experimentation in order to show that O<sub>4</sub> exists and prepare compositions that would enable O<sub>4</sub>, if it does exist, to be stable enough to be used in medical treatment.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Applicant's sole argument is claims 89-132 were cancelled. However, the Applicant has not cancelled the claims as the amendment only cancelled claims 1-88 and added new claims which have been renumbered as claims 133-149. Although, the Applicant did not apply the Declaration (8/10/2009) to traverse this rejection, the Examiner addresses the same. Said Declaration does not overcome the rejection as the declaration makes no attempt and does not provide any evidence to refute the basis of the enablement rejection herein that tetrameric oxygen does not exist or at most is so unstable that it would be impossible to use in a medical treatment. As such, the rejection herein is maintained.

Claims 133-149 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended claims do not recite the presence of tetrameric oxygen. However, Paragraph 0009 of the Specification, clearly states that "The invention therefore provides methods, apparatuses and systems for delivering tetrameric oxygen to tissues". Further, nowhere in the Specification and claims as originally filed was it disclosed that the composition is in the form of a gas. As such, there is indication that the inventors, at the time the application was filed, contemplated an invention which is devoid of tetrameric oxygen or an invention where gaseous oxygen was administered.

Claims 133-149 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing oxygen levels in a tissue of an individual with composition which is a gas and contains about 10% to about 25% free available oxygen by volume, does not reasonably provide enablement for any other formulation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 133-149 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

*The nature of the invention:*

The invention is directed to a method of increasing oxygen levels in a tissue of an individual by administering a composition which comprises between about 10% and about 25% free available oxygen by volume.

*The state of the prior art and the predictability or lack thereof in the art:*

The prior art does not disclose a composition which comprises between about 10% and about 25% free available oxygen by volume other than as gas. Supersaturated aqueous solutions of dissolved oxygen under pressure in bottles are on the order of low hundreds of ppm or less, which oxygen begins to escape into the atmosphere as soon as the bottle is opened. See e.g. Nestle et al., page 3363, Table 1, Page 3364, Fig. 3. As such, there is insufficient evidence to support the assertion that the disclosed aqueous tetrameric oxygen solution or the other disclosed formulations would contain a concentration of oxygen of about 10% by volume to about 25% by

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volume which equates to about 100,000 ppm to about 250,000 ppm of dissolved oxygen. As such, predictability in the art appears to be low as to suitable dosage forms which are not gases.

*The amount of direction or guidance present and the presence or absence of working examples:*

The Specification does not provide any guidance as to a composition which comprises between about 10% and about 25% free available oxygen by volume as the "oxygen" identified in the Specification is tetrameric oxygen which as indicated above is not enabled by the Specification. Further, the "composition" disclosed is an aqueous solution which purportedly contains 25% dissolved oxygen as tetrameric oxygen and is a dietary supplement (Specification, paragraph 0010). Paragraph 0010 indicates that the term "composition" wherever set forth in the Specification refers to the composition disclosed in paragraph 0010 of the Specification. However, the Specification does not disclose how the composition which is an aqueous solution can be delivered as gel, solid, semi-solid, paste, lotion, mists, spray, foams, suppositories, emulsion, sustained release form, transdermal patch or body wrap and still retain the purported amount of dissolved tetrameric oxygen and does not disclose how a dietary supplement can be made suitable as an injection.

*The breadth of the claims and the quantity of experimentation needed:*

The Claims are broad in that they claim a free available oxygen concentration of about 10% to about 25% by volume which includes formulations other than gases. As such, one ordinary skill in the art would be required to do undue experimentation in order to formulate the described aqueous solution of tetrameric oxygen into other formulations while retaining the purported amount of free available oxygen concentration by volume.



The Examiner had duly considered the Applicant's arguments and Declaration (8/10/2009) but deems the same unpersuasive.

The Applicant argues that the claimed invention is enabled and submits evidence showing that application of a hyperbaric oxygen solution oxygenated retinal cells, ARPE-19 cells and ischemic rabbit eyes. However, the declaration provides no evidence that said solution contains an amount of oxygen that falls within the claimed range of about 10% and about 25% free available oxygen. Further, the claims are not limited to solutions. As such, in light of the fact that the claimed amount of oxygen is an impossibility where the composition is not a gas and the Specification does not disclose how the aqueous tetrameric oxygen solution can be converted into other formulations while retaining the purported amount of dissolved oxygen, said declaration is not commensurate in scope with the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The claimed invention is directed to methods of increasing oxygen levels in a tissue by administering a composition comprising between about 10% and about 25% free available

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oxygen by volume, where the tissue can be hypoxic tissue, eye tissue, the individual is suffering from a medical condition of the eye or pain, and where the patient can be treated with gene therapy.

Claims 133, 143-149 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Muller.

Muller expressly discloses that air is composed about 21% by volume of oxygen (see entire document) which falls within the scope of applicant's claims.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978). See also *Ex parte Novitski*, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993). Muller discloses that air is composed about 21% by volume of air. The difference between Muller and the claimed invention is that Muller does not expressly disclose a method of increasing oxygen levels in a tissue of an individual comprising administering a composition which comprises about 10% to about 25% free available oxygen by volume. However, since air contains about 21% by volume of oxygen it is inherent that an individual falling within the scope of the claims will come into contact with air which is a composition which contain a volume of free oxygen falling within the claimed range. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

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*Conclusion*

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
October 1, 2009

/Johann R. Richter/  
Supervisory Patent Examiner, Art Unit 1616